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**APPLICATION NUMBER: 60/561,378**

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**RELATED PCT APPLICATION NUMBER: PCT/US05/12122**



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# PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

22264 U.S. PTO  
60/561378

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TITLE OF THE INVENTION (280 characters max)					
MULTI-SITE INJECTION SYSTEM					
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<input checked="" type="checkbox"/> Customer Number		26822		 PATENT TRADEMARK OFFICE	
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ENCLOSED APPLICATION PARTS (check all that apply)					
<input checked="" type="checkbox"/> Specification	Number of Pages	7	<input type="checkbox"/> CD(s), Number		
<input checked="" type="checkbox"/> Drawing(s)	Number of Sheets	2	<input checked="" type="checkbox"/> Other (specify)	ASSIGNMENT; COVER SHEET	
<input type="checkbox"/> Application Data Sheet. See 37 CFR 1.76					
METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT (check one)					
<input checked="" type="checkbox"/>	A check or money order is enclosed to cover the filing fees				FILING FEE AMOUNT (\$)
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The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.					
<input checked="" type="checkbox"/>	No.				
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Respectfully submitted,

SIGNATURE

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Date 04/12/2004

REGISTRATION NO. 27,792

(if appropriate)  
Docket Number: 3149P

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P19LARGE/REV05

MULTI-SITE INJECTION SYSTEM

The present invention is generally directed to the administration of a medicament and is more particularly  
5 directed to a multi-site injection system for dermal delivery of a medicament.

SUMMARY OF THE INVENTION

10 A multi-site injection system in accordance with the present invention generally includes a rotatable drum having an outer surface with microprotrusions thereon.

The micro-protrusion may include passages, or lumens,  
15 therethrough for enabling transport of a medicament therethrough from an inner surface of the rotatable drum and into a stratum corneum of a user. Alternatively the microprotrusion may be solid and coated with the medicament.

20 A fixed inner drum is provided for supporting the rotatable drum and includes at least one radial opening therein for providing the medicament to the microprotrusions.

A supply of medicament is disposed within the inner drum  
25 and a housing is provided for supporting the rotatable drum and the inner drum. The housing includes an opening for exposing an arcuate portion of the rotatable drum in order to enable rotation of the rotatable drum by rolling the rotatable drum against a users skin.

While not shown, a blatter may be provided for containing the medicament with the blatter being in fluid communication with the radial opening in a fixed inner drum for providing a  
5 medicament to the microprotrusion passages.

Preferably, the medicament comprises botulinum toxin.

#### BRIEF DESCRIPTION OF THE DRAWINGS

10

The advantages and features of the present invention will be better understood by the following description when considered in conjunction with the accompanying drawings in which:

15

Figure 1 is a perspective view of a multi-site injection system in accordance with the present invention generally showing a housing, or shell, for supporting a rotatable drum along with a rotatable drum having an outer surface with  
20 microprotrusions therein, a port is also shown which provides an access for charging the system with a medicament to be injected, such as, for example botulinum toxin;

Figure 2 is a partial cross section of the system shown  
25 in Figure 1 more clearly illustrating a fixed inner drum for containing a medicament and at least one radial opening therein for providing medicament to a plurlaity of microprotrusions affixed to and rotatable with the rotatable drum.

The rotatable drum is rotated by rolling the drum against a users skin, not shown. The housing supporting the rotatable drum and the inner drum includes an opening for exposing an  
5 arcuate portion of the rotatable drum for enabling rotation thereof; and

Figure 3 is a cross sectional view taken along line 3-3 of Figure 2 more clearly showing operation of the system.

10

#### DETAILED DESCRIPTION

With reference to Figure 1, there is shown a multi-site injection system 10 which includes a rotatable drum 12  
15 including an outer surface having a plurality of microprotrusions, or needles, affixed thereto. The microprotrusions may have lumens, or passages, therethrough.

A housing 20 is provided for supporting the rotatable drum along with a fixed inner drum 24, see Figures 2 and 3. An arcuate opening 28 in the housing 20 is provided for exposing the drum surface 14 which enables rotation of the drum 12 by rolling the drum 12 against a users skin 42.

25 Also shown in Figure 1 is an access 34 which is provided for introducing a medicament, such as botulinum toxin into the system via a syringe, not shown, or other suitable conveyance.

As more clearly shown in Figures 2 and 3, an inner drum, fixed to the housing, or shell, 20, is provided for containing a supply of medicament instilled through the access port 30 as hereinabove noted.

5

This nonrotating inner drum, or reservoir, 36 includes a plurality of radial passages, or openings, 38 for providing the medicament 36 to the needles 18.

10

Preferably, a sponge-like material 40 is disposed on the rotatable drum 12 for both distributing medicament provided through the radial openings 18 and enabling application of the medicament via the needles 18 without excess medicament being deposited on the users skin 42.

15

In operation, rotation of the drum 12 on the users skin 42 causes rotation of the drum as indicated by the arrow 44 and medicament flows into the sponge and is applied to the users skin 42. The needles penetrate the stratum corneum, or skin, 42 of the user, thus introducing the medicament thereinto.

20

Alternatively, the protrusions, or needles may include lumens therethrough for direct transport of medicament 36 from the inner drum 34 upon rotation of the drum 12 against the users skin 42.

25

Although there has been hereinabove described a specific multi-site injection system in accordance with the present

invention for the purpose of illustrating the manner in which the invention may be used to advantage, it should be appreciated that the invention is not limited thereto. That is, the present invention may suitably comprise, consist of,  
5 or consist essentially of the recited elements. Further, the invention illustratively disclosed herein suitably may be practiced in the absence of any element which is not specifically disclosed herein. Accordingly, any and all modifications, variations or equivalent arrangements which may  
10 occur to those skilled in the art, should be considered to be within the scope of the present invention as defined in the appended claims.



## WHAT IS CLAIMED IS:

1. A multi-site injection system comprising:
  - a rotatable drum having an outer surface with  
5 microprotrusions thereon, said microprotrusions having lumens  
therethrough for enabling transport of a medicament  
therethrough from an inner surface of said rotatable drum and  
into a stratum corneum of a user;
  - a fixed inner drum for supporting said rotatable  
10 drum and having at least one radial opening therein for  
providing said medicament to the microprotrusion lumens;
  - a supply of said medicament disposed within the  
inner drum; and
  - a housing for supporting the rotatable drum and the  
15 inner drum, said housing having an opening for exposing an  
arcuate portion of said rotatable drum in order to enable  
rotation of said rotatable drum by rolling said rotatable drum  
against a user's skin.
- 20 2. A multi-site injection system comprising:
  - a rotatable drum having an outer surface with  
microprotrusions thereon and radial opening for transport of a  
medicament therethrough;
  - a fixed inner reservoir for storing the medicament  
25 and for supporting said rotatable drum, the reservoir having  
at least one radial opening therein for release of the  
medicament;
  - a sponge layer covering said rotatable drum for  
receiving medicament as the rotated drum is pressed and

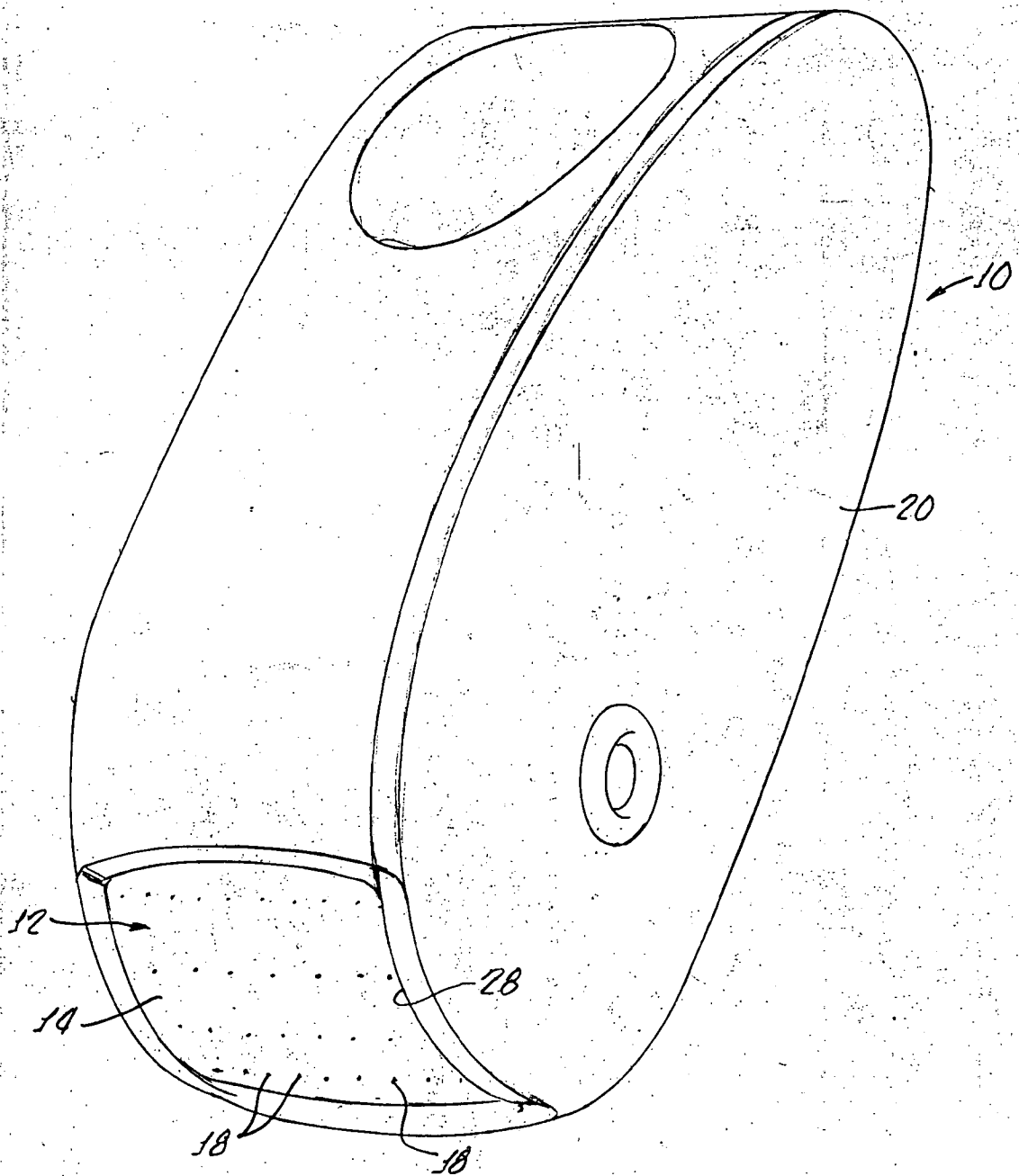
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rotated across a user's skin and enabling said microprotrusions to deliver the medicament by penetrating of the stratum corneum of the user.

5           3.    The system according to claim 2 wherein said sponge layer is fixed to said rotatable drum.

          4.    The system according to any one of claims 1-3 wherein said medicament comprises botulinum toxin.

10

FIG. 1

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FIG. 2.

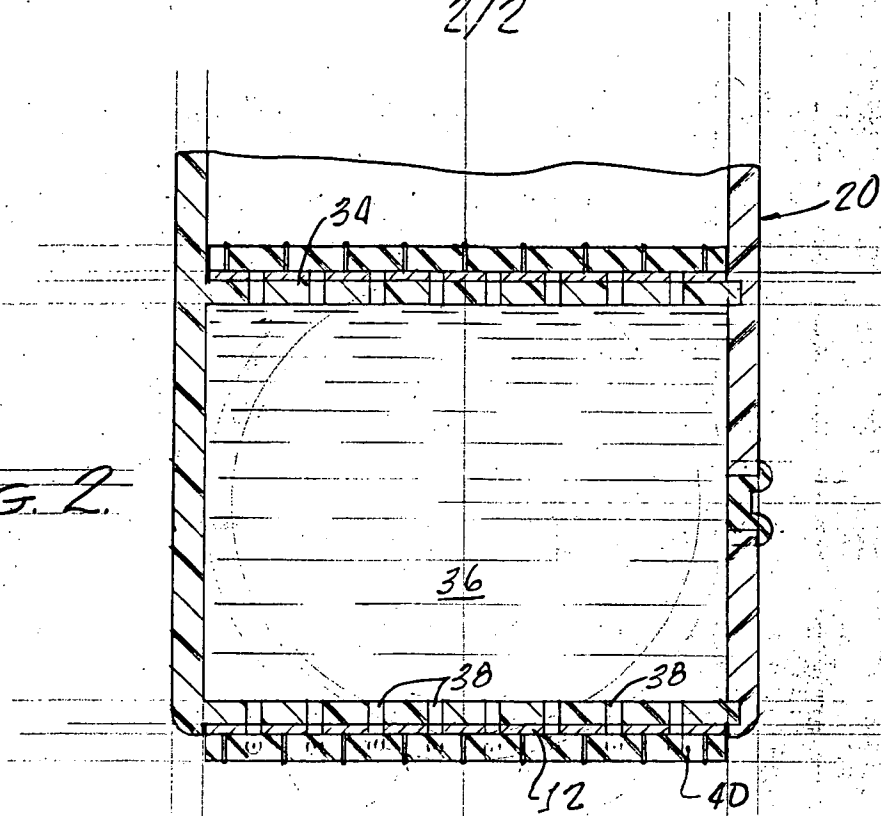


FIG. 3.

